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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,892	02/14/2002	Bradley L. Christenson	19654-243493	4377

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,892	CHRISTENSON ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response filed 7/21/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao et al (USPN 4,863,743) in combination with Chang et al (USPN 5,035,898). The claims are drawn to a tablet and a process of making. The tablet comprises granules. The granules are coated with a thermoplastic cellulose ether. The granules consist of potassium chloride. The process for making comprises wet-granulation in order to coat the granules with ethyl-cellulose (the cellulosic ether) and tableting of the granules.

Hsiao et al teaches an extended release tablet containing granules comprising potassium chloride and ethyl cellulose. The ethyl cellulose used by the reference has a viscosity ranging from 6 – 40 cP. The tablet contains 20mEq of potassium, and would be administered to a patient in need in order to supplement their potassium requirements (col. 3, lin. 54 – 60; col. 4, lin. 51 – 68; col. 5, lin. 43 – 56). The examples of the reference include other excipients, yet the reference

discloses that these excipients are completely optional. Barring a comparative showing of unexpected results, and criticality to the composition being substantially free of surfactants and other agents, it is the position of the examiner that these limitations do not impart patentability, and does not distinguish the claimed invention form the prior art.

With regard to claims 7, 8, 13, 14 and 28 which are drawn to tablets containing specific concentrations of potassium chloride and ethyl cellulose. Claims 7 and 13 recite the tablets to have approximately 17.4% potassium chloride, while claim 8 and 14 recite the tablet to have a concentration of 13.5%. The reference teaches the potassium chloride to be present in a concentration of 79%, and in dosage of 15 mEq with an ethylcellulose content of 11.9%. It would be obvious to one of ordinary skill ion the art to modify the formulation to achieve the optimal results. Furthermore applicant is reminded that merely reciting the optimal working ranges in a composition does not impart patentability, when the general conditions of the composition are met. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Hsiao et al teaches a tablet comprising granules of potassium chloride coated with ethyl cellulose. The reference teaches that the granules are coated in a fluidized bed, with a solvent solution including methyl alcohol and distilled water. The solvents are removed during the drying step, which provides granules coated with ethyl cellulose. As discussed above the reference discloses that the tablet can optionally contain excipients. The reference is silent to the dew point temperature at which the coating process occurs. The use of a fluidized bed to create coated particles is well known in the art, and the temperature at which the coating occurs can vary depending upon the practitioners. These variations can be determined through routine experimentation by one of ordinary skill in the art.

The reference provides identical granules to those of the claimed invention, produced by the same process (a fluidized bed) as applicant's the burden is now shifted to applicant to show a patentable difference between the two. Identical products are made through similar processes it is now upon the applicant to show the patentable distinction of the two granules. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to claims 31 – 34 which recite a process for making tablets where disintegrants and further excipients are included in the tableting steps, it is the position of the examiner that these claims are also obviated. The inclusion of disintegrants and other excipients is well know in the art and can be seen in Chang et al. The reference discloses potassium chloride granules coated with a cellulosic polymer (col. 2, lin. 7 – 30). The granules are between 30 and 50 mesh and are coated in a fluidized bed, and compressed into tablets with microcrystalline cellulose and croscarmellose (col. 2, lin. 48 – 66).

With this in mind one of ordinary skill in the art would be motivated to follow the teachings and suggestions of the art in order to produce coated granules that allowed for more optimized bioavailability. A skilled artisan seeing the knowledge in the art to modify a fluidized bed process as exhibited by Hsiao, or Chang; would be motivated to modify the concentrations and temperature of the process in order to optimize the output of coated granules and tot maximize the bioavailability of the final product. A skilled artisan would have been motivated to include the excipients of Chang into a tablet formulation in order to impart stability on a formulation. It would have been obvious to a skilled artisan to follow the teachings and suggestion in the art with an expected result of a process, which produces coated potassium chloride granules, along with tablets comprising well-known excipients.

Response to Arguments

2. Applicant's arguments filed 7/21/03 have been fully considered but they are not persuasive. Applicant argues that:

a. Since Hsiao discloses a granule merely comprising ethylcellulose (along with hydroxypropylcellulose and propylene glycol), the reference cannot obviate the granule of the instant claims

b. Hsiao does not provide a 15mEq dosage form, and provides no suggestion to such a dosage amount.

With regard to argument a., applicant is reminded that though Hsiao includes other cellulosic compounds in the coating composition, it does include ethylcellulose with the appropriate viscosity and physical properties. Applicant has yet to provide unexpected or surprising results, which would distinguish the coated granules of the instant claims from those of the prior art. The granules of the instant claims contain ethyl-cellulose, as do the granules of Hsiao and Chang. Applicant has yet to establish a functional, and patentable difference between the granules and subsequent tablets of the prior art (Hsiao) and those of the instant invention. Applicant has provided no criticality to the granule coating composition, and has not established a patentable distinction between the compositions. With regard to process claims 17 and 31, Hsiao discloses a fluidized bed process comprising spraying and drying (example 1), which is identical to the process of applicant save for the dew point value. Again applicant has not placed criticality on the dew point value within the process. The instant claims are within the same field of endeavor (producing potassium chloride dosage forms) and are producing identical compositions. Burden is placed on applicant to provide evidence to a patentable difference within the composition that places criticality on the dew point of the coating process.

3. With regard to argument b., Hsiao discloses 10mEq and 20mEq and not 15mEq dosage forms of the potassium chloride tablets, it is the position of the examiner that these dosage units

can be obtained through routine experimentation and are within the level of skill in the art. 15mEq dosage forms are available for other drugs that are associated with potassium chloride such as magnesium salts (Chang). A skilled artisan would be able to obtain such a dosage if the need arose. Further applicant argues that the 15mEq dosage is for the purpose of delivering a twice-a-day total dosage of 30mEq where 40mEq may be too much for a patient. The dosage would be symmetrical and (two 15mEq dosages) and be easier to handle. Yet this is not represented in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). A skilled artisan would be able to determine an appropriate dosage for the associated disorder, and decide the proper dosage units. For these reasons the rejections under Hsiao remain and the claims remain obviated.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
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